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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,719

04/30/2007

Sheetal Mansukhlal Shah

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08/31/2010

Syngenta Crop Protection, Inc.,
Patent and Trademark Department
410 Swing Road
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EXAMINER

HIRIYANNA, KELAGINAMANE T

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

08/31/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,719	Applicant(s) SHAH ET AL.	
	Examiner KELAGINAMANE HIRIYANNA	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/06 & 09/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on 05/25/2010 in response to office action mailed on 04/27/2010 has been acknowledged.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Restriction of invention

Applicant's election without traverse of restriction requirement in the reply filed on 05/25/2010 is acknowledged and the amendment thereof is entered. Applicant elects without traverse the invention of Group I (Claims 1-6), drawn to a Transgenic insect or cell wherein the level of expression of dhr96 or a homologue thereof has been reduced through RNAi in the reply filed on 05/25/10 for further prosecution on merits is acknowledged.

Claim 2, 3 and 5 are amended.

Claim 4 is cancelled.

Applicant's election of species *Drosophila* in the reply filed on 05/25/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-3 and 5-6 are pending and presently under examination.

Claims 7-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected claims, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on.

It is noted that initially from the claims, it appeared that invention was limited to RNAi as the method of changing the level of expression of dhr96 or homologues thereof; however, upon further consideration of the specification (e.g., p.3, paragraph 1), what is meant to be encompassed by transgenic is actually broader than simply RNAi, but also

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includes, at least, insertional mutagenesis. Hence, while invention I was previously listed as limited to RNAi, it is now considered to include any form of transgenesis.

Specification

Abstract:

The abstract is objected to for not conveying the claimed and elected invention to make the Artisan aware that such is the invention. To wit, the abstract describes methods of utilizing the claimed transgenic cells/insects, but does not convey that the cells/ insects are invented subject matter.

Claim interpretation

Claim 1 appears much larger in scope than perhaps the applicant intends. The claim 1 compares expression levels of a dhr96 or any homologue thereof, optionally, in any transgenic insects to any insect cell, transgenic insect cells to any insect, and transgenic insect to any other insect.

However, because the scope in claim 1 is sufficiently clear, the claim is being interpreted encompass the following.

a) a transgenic insect, wherein the level of expression of dhr96 or dhr96 homologue is lower than the level of expression of any dhr96 or any dhr96 homologue in any insect homologues thereof.; and

b) a transgenic insect cell wherein the level of expression of dhr96 or dhr96 homologue is lower in level than the level of expression of any dhr96 or dhr96 homologue in any insect or cell thereof.

Claim Objection

Claims 2, 3, 5, and 6 are objected to because of the following informalities: The claims utilize article "A", while being dependent from Claim 1. Proper antecedent basis is to recite "The". However, because the claims are sufficiently clear for their scope, non rejection is made for lack of clarity. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 recites that the homologue is *Drosophila*. However, claim 1 refers to homologue of dhr96. Hence, the scope of what is being claimed is not clear. However, for substantive purposes Claim 2 will be considered to encompass homologues of dhr96 in transgenic and non-transgenic *Drosophila* cells and transgenic and non-transgenic *Drosophila*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5 and 6 are rejected under 102(b) as being anticipated by Lam et al., (2000, Current Biology 10:957-963).

The above claims are drawn to a transgeneic insect or insect cell wherein the level of expression of dhr96 or homologue thereof has a reduced relative to the level of expression of dhr96 or its homologue in a non-transgenic insect of non-transgenic insect cell.

Lam teaches a method of reducing the expression of ecdysone receptor (a well known homologue of dhr96) in a Drosophila species that is transgenic for the dsRNA expression construct by the way of RNA interference and the cells derived from the same were also had the reduced cellular levels of EcR expression (entire article; abstractp.961-962). The cited art thus clearly anticipates the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5 and 6 are rejected under 35 USC 103 (a) as being unpatentable over Lam et al., (2000, Current Biology 10:957-963) in view of Fisk et al (proc. Natl. Acad. Sci. USA 92:10604 -10608) and Kalidas, et al. (2002, Neuron, 2: 177-84)..

The above claims are drawn to a transgenic insect or insect cell wherein the level of expression of dhr96 or homologue thereof has a reduced relative to the level of expression of dhr96 or its homologue in a non-transgenic insect or non-transgenic insect cell.

Lam teaches a method of reducing the expression of ecdysone receptor (a well known homologue of dhr96) in a Drosophila species that is transgenic for the dsRNA expression construct by the way of RNA interference and the cells derived from the same were also had the reduced cellular levels of EcR expression (entire article; abstractp.961-962). Lam however, does not teach dhr96 and Drosophila melanogaster.

Regarding claims Fisk teaches cloning and expression of dhr96 gene and its several of its homologues from Drosophila.

Kalidas teaches that using cDNA of gene one can generate a knockdown of the expression of a Drosophila melanogaster's genes by the method of RNA interference. Kalidas also teaches using knockout methods for generating the same (p.177)

Thus it would have been obvious for one of ordinary skill in the art to substitute a generic gene or cDNA in the expression constructs for RNAi interference method of Lam or Kalidas with the dhr96 cDNA and express the dhr96iRNA in Drosophila melanogaster

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and reduce levels of expression of dhr96 in said transgenic *Drosophila melanogaster* relative to its expression in wild type *Drosophila*. One of ordinary skill in the art would have reasonable expectation of success making using a transgenic *drosophila* with a relatively reduced level of expression of dhr96 or its homologue because the art teaches it is routine use RNA interference or knockdown or knockout of a targeted gene in order to reduce its expression in the transgenic organism or a cell. Thus, the claimed invention was *prima facie* obvious.

Claims 1-3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Capecchi, et al. (1994) *Scientific American*, 270: 34-41 (art of record) and Fisk, et al. (1995) *Proceedings of the National Academy of Sciences, USA.*, 92(23): 10604-608; and Kalidas, et al. (2002) *Neuron*, 2(17): 177-84.

Capecchi teaches knockout technology applied to mice, specifically with respect to the disruption of HoxA-3 gene and a method of producing the same. Such applies to determining the *in vivo* function of any known gene of interest. For example, Capecchi discloses the applicability of gene targeting to many other genes, so that a correlation can be drawn between the malfunctioning gene to the manifestation of disease (e.g., p. 41, col. 2, paragraph 2). Capecchi further discloses the components of a targeting vector (e.g., p. 38, col. 3, and p. 39, cols. 10-2). Further disclosed are the steps for targeted gene replacement in ES cells as well as in mice (e.g., pp. 36-39 and diagrams). However, Capecchi does not teach doing so in *Drosophila melanogaster*, or the genes of such animal.

However, Fisk teaches the discovery of the new gene dhr96 in *Drosophila*, which is a nuclear hormone receptor.

Kalidas demonstrates that the RNAi gene knock-out allows for similar determination of phenotype in *Drosophila Melanogaster* (ABSTRACT).

Kozlova, et al. (2003) *Methods in Enzymology*, 364: 475-490, describes several methods of knocking-out nuclear receptors in *drosophila* (e.g., pp. 484 et seq.).

Hence, its obvious because the gene was known, it was standard in the Art to perform knock-out transgenesis of genes in cells and animals, including those of *D.*

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melanogaster, to find the function of the gene. The Artisan would have been motivated to do so to determine the functions of dhr96. Moreover, the Artisan would have had a reasonable expectation of success as the Art is being utilized for its art-recognized purposes. Thus, the claimed invention was *prima facie* obvious.

Conclusion:

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanne Ph.D.*, whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at **(571) 272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/Robert M Kelly/

Primary Examiner, Art Unit 1633